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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

MAY - 1 2003

FEDERAL EXPRESS

WARNING LETTER

Mr. Gary Lee
President
LightMed Corporation
No. 1-1, Lane 1
Pao-an St. Sec. 3
Shulin City, Taipei
Taiwan

Ref:OC:I1-1934

Dear Mr. Lee:

This letter is written to advise you of items of noncompliance with the Federal laser product performance standard encountered during review of the LightLas 532 Ophthalmic Photocoagulator Laser product report, dated 11/1/2001, Accession Number 0122320.

1. Calibration procedures and schedule

The LightLas Laser Operator's manual lacks the calibration procedures and schedule, which are required to be supplied with each Class III and IV medical laser product under 21 CFR 1040.11(a)(2). Although we would not object to your inclusion of statements such as you have to the effect that only authorized representatives of LightMed may perform the procedure and that user recalibration would invalidate the warranty, the requirement is clear that the instructions must be supplied to the purchaser. You will note that the IEC 60825 standard has a similar requirement.

For your information, the Operator's manual for your Lpulsa SYL-9000 Ophthalmic YAG laser complies with the calibration procedures and schedule requirement.

2. Annual Report

You have not filed the 2001 annual report with the FDA for the Lpulsa, LightLas, and any other laser products, as required under 21 CFR 1002.13.

Please investigate the problems and determine the extent of these failures. In accordance with 21 CFR 1003.11(b), you must notify us of the total number and location of units produced (including identification of all models and brands involved) and the approximate number that have left the place of manufacture. If there are other products with similar violations, you are to include them in your notification to us. In addition, if the product distribution was confined to specific geographical areas of the United States

(U.S.), please specify those areas. You must respond in writing within 15 days of receipt of this letter. Your response should pursue one of the options listed below:

1. Refutation - You may submit your views and evidence in accordance with 21 CFR 1003.11(a)(3) to establish that the alleged noncompliances do not exist, do not relate to the safety of the product, or are directly attributable to user abuse or lack of maintenance. Should you choose to refute the allegations of noncompliance, you will have an opportunity to request a hearing under 21 CFR Part 16.

2. Exemption Request - If you do not refute the alleged noncompliances, in accordance with 21 CFR 1003.30, you may request an exemption from the requirements of user and dealer/distributor notification found in 21 CFR 1003.10(b). You must include the grounds upon which such exemption is requested. Please see 21 CFR 1003.31 for further information on what constitutes reasonable grounds for an exemption. Also indicate all models and brands that are to be covered by the exemption, along with the number produced and dates of production.

3. Purchaser Notification and Corrective Action - If you neither refute the alleged noncompliances nor request an exemption, then you will be required to (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) showing how you will fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products at no charge to the user.

    a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to this office. It is recommended that you submit a draft of any letters to us for review and concurrence prior to mailing. Please submit such drafts with your response to this letter, because, under 21 CFR 1003.11(c), you will have only 14 days to furnish the notification to purchasers and dealers/distributors once we direct you to begin notification.

    b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, and 1004.4. Such a plan must expeditiously correct the noncompliance and must be approved by FDA. (See 21 CFR 1004.6)

If you request additional time to investigate the extent of the problem or to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you

may be required by 21 CFR 1003.11(c) and 1003.21 to proceed with interim notification to affected persons. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

Failure to respond to this letter or to correct these products in a timely manner can result in regulatory action being initiated by the FDA without further notice. These actions may include, but are not limited to, an injunction and/or imposition of civil penalties as provided for in Section 539 of the Federal Food, Drug, and Cosmetic Act (21 USC § 360pp). Persons failing to correct violations are subject to civil penalties of up to $1,000 per violation and up to a maximum of $300,000.

You are reminded that the above items relate to products already introduced into U.S. commerce. You should address matters concerning production units under separate cover. You must supplement your product report(s) to identify the steps you are taking to assure that present production meets all applicable federal requirements. This supplement must be received prior to any further introduction into commerce, as it is unlawful to introduce into commerce any electronic product which does not comply with an applicable standard (21 USC § 360oo(a)(1)).

Your response should be sent to: Director, Division of Enforcement B (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850 USA. You are also requested to send a copy of your response to: Director, Compliance Branch, Food and Drug Administration (HFR-PA250), 19900 MacArthur Blvd., Suite 300, Irvine, CA 92615-2445 USA. If you have further questions on these requirements, please contact Ms. Cory Tylka of the Electronic Products Branch at (301) 594-4595.

Sincerely yours,

for Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

CC: Ms. Michelle P. Lee
President
LightMed Corp.
703 Avenida AZOR
San Clemente, CA 92673